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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,529	07/16/2003	Lukas Eisermann	4002-3359/PC635.02	8968
5514 7590 08/24/2007 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 08/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/620,529	Applicant(s) EISERMANN ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-50, 62-65, 68-78 and 80-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-50, 62-65, 68-78 and 80-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41-50, 62-65 and 68-83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-36 of copending Application No. 10/774,135 and claims 1-40 of copending Application No. 11/299,115. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending applications are more specific and are thus a "species" of the "generic" invention. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Drawings

Due to the numerous subjects discussed in the interview on May 14th, 2007, either there was confusion on the applicant's or examiner's part in the discussion related to the drawings. While, using the term "engageable" does overcome the 35 U.S.C. 101 rejection with regards claim 77, it does not solve the deficiency that the drawings fail to show structure claimed.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation of engaging a bone screw with the prosthetic joint and vertebra must be shown or the feature(s) canceled from the claims 77, 78 and 83. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action.

Claim Rejections - 35 USC § 101

The amendment to claim 77 filed on May 30th, 2007 is acknowledged and accepted by the examiner. The corresponding 35 U.S.C. 101 rejection is hereby withdrawn.

Claim Rejections - 35 USC § 112

The amendment filed on May 30th, 2007 canceling claim 79 is acknowledged and accepted by the examiner. The corresponding rejection under 35 U.S.C. 112, 1st paragraph is hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41-44, 73, 74, 76, 81 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aesculap AG & Co. (DE 299 114 22 U 1) in view of Fraser et al (US Patent 6,592,624).

Aesculap discloses a device (**Figures 1-7**) comprising: a first bearing surface (**5**); a second bearing surface (**13**); a flange (**6**) projecting from the first bearing surface (**5**); a flange (**14**) projecting from the second bearing surface (**13**); the flanges (**6, 14**) are centrally located and have a length that extends substantially entirely along the bearing

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surfaces (5, 13); and a first articular surface (12) interfacing with a second articular surface (25) both located opposite the first and second bearing surfaces respectively. It is noted that the device is inherently capable of being inserted in-between two vertebral bodies at any rotational sense such as at a lateral orientation.

Aesculap fails to disclose the flanges (6, 14) being tapered in a direction parallel to the bearing surfaces along at least a portion of its length. Fraser et al teach (**Figures 1-11**) flanges (18) that taper as applicant has claimed and disclosed. Fraser et al explain that the wedge-shape along with proper orientation of all flanges improves insertion and holding capability of the prosthetic joint. It would have been obvious to one having ordinary skill at the time of invention to design the flanges of Aesculap with the tapered shape applicant has claimed and taught by Fraser et al to improve insertion and implantation fixation.

Claims 45-49, 62-64, 68-72 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aesculap in view of Fraser et al and in further view of Michelson (US Patent 5,609,635).

The combination of Aesculap and Fraser et al disclose and teach all of the claimed limitations except for holes passing through the flange allowing for bone growth to enter and further comprising a bone growth substance to facilitate the bone growth. Michelson teaches (**Column 2, Lines 9-11; Lines 29-35; Column 6, Lines 56-66; Column 8, Lines 38-46**) that openings of random size, shape, and distribution passing partially or entirely through along with being composed or treated with materials for microscopic bone in-growth enhance stability of the implant within bone. It would have

been obvious to one having ordinary skill in the art at the time the invention was made to create through holes as shown in **Figure 1** of Michelson composed/treated with bone growth materials throughout the combination of Aesculap and Fraser et al in order to improve implant fixation.

Claims 50 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aesculap in view of Fraser et al and in further view of Michelson and Gill et al (US Patent 6,113,637).

The combination of Aesculap, Fraser et al and Michelson disclose and teach all of the claimed limitations except for an indent on one of the articular surfaces. Gill et al teach (**Column 2, Lines 32-38; Column 6, Lines 31-64**) that an indent (52) provides translation between the two articular surfaces thereby avoiding jamming which in turn leads to wear provoking pain and/or accelerated degeneration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for an indent as taught by Gill et al to the combination of Aesculap, Fraser et al and Michelson in order to avoid damage to the implant and/or pain to the subject.

Claims 77, 78, 80 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aesculap in view of Fraser et al and in further view of Graham (US Patent 5,246,458).

The combination of Aesculap and Fraser et al disclose and teach all of the claimed limitations except for a bone screw that engages the implant and the vertebra. Graham teaches (**Column 2, Line 65 through Column 3, Line 2; Column 4, Lines 6-13**) screws being placed into members protruding into adjacent vertebral bodies in order

to provide for a secure fixation of the implant within the spinal column. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for screws to securely fix the flanges of the combination of Aesculap and Fraser et al within adjacent vertebral bodies to maintain proper placement and orientation.

Claims 77, 78, 80 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aesculap in view of Fraser et al and in further view of Ferree (US Patent 6,706,068).

The combination of Aesculap and Fraser et al disclose and teach all of the claimed limitations except for a bone screw that engages the implant and the vertebra. Ferree teaches (**Column 3, Lines 57-65**) that screws are used to fix the flanges of his implant (**Figure 4**) to the vertebrae. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for holes in the flanges to allow for screws to pass through thereby fixing the implant in a fixed position and orientation relative to the vertebrae.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
August 18th, 2007



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